

YOUNG CONAWAY STARGATT & TAYLOR, LLP

BEN T. CASTLE
 SHELDON N. SANDLER
 RICHARD A. LEVINE
 RICHARD A. ZAPPA
 FREDERICK W. IOBST
 RICHARD H. MORSE
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 CRAIG A. KARNSNITZ
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 JEROME K. GROSSMAN
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 DANIELLE GIBBS
 JOHN J. PASCHETTO
 NORMAN M. POWELL
 ELENA C. NORMAN
 EDMON L. MORTON
 JOHN E. TRACEY

THE BRANDYWINE BUILDING
 1000 WEST STREET, 17TH FLOOR
 WILMINGTON, DELAWARE 19801
 P.O. BOX 391
 WILMINGTON, DELAWARE 19899-0391
 (302) 571-6600
 (800) 253-2234 (DE ONLY)
 FAX: (302) 571-1253
 110 WEST PINE STREET
 P.O. BOX 594
 GEORGETOWN, DELAWARE 19947
 (302) 856-3571
 (800) 255-2234 (DE ONLY)
 FAX: (302) 856-9338
 WWW.YOUNGCONAWAY.COM
 DIRECT DIAL: 302-576-3587
 DIRECT FAX: 302-576-3551
 jcastellano@ycst.com

JOSEPH M. BARRY
 RYAN M. BARTLEY
 SEAN M. BEACH
 DONALD J. BOWMAN, JR.
 MICHELE SHERRETTA BUDICK
 JEFFREY T. CASTELLANO
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 NATHAN D. GROW
 STEPHANIE L. HANSEN
 JAMES L. HIGGINS
 PATRICK A. JACKSON
 DAWN M. JONES
 KAREN E. KELLER

SPECIAL COUNSEL
 JOHN D. MC LAUGHLIN, JR.
 KAREN L. PASCALE
 SETH J. REIDENBERG
 PATRICIA A. WIDDSS

JENNIFER M. KINKUS
 EDWARD J. KOSMOWSKI
 EVANGELOS KOSTOULAS
 JOHN C. KUFFEL
 TIMOTHY E. LENGEK
 ANDREW A. LUNDGREEN
 MATTHEW B. LUNN
 ADRIA B. MARTINELLI
 KATHALEEN MCCORMICK
 TAMMY L. MERCER
 MARIBETH L. MINELLA
 D. FON MUTTAMAKA-WALKER
 MICHAEL S. NEIBURG
 (PA & NJ ONLY)
 JENNIFER R. NOEL
 ADAM W. POFF
 ROBERT F. POPPITI, JR.
 SARA BETH A. REYBURN
 CHERYL A. SANTANIELLO
 MICHAEL P. STAFFORD
 RICHARD J. THOMAS
 MARGARET B. WHITEMAN
 SHARON M. ZIEG

SENIOR COUNSEL
 CURTIS J. CROWther

OF COUNSEL
 BRUCE M. STARGATT
 STUART B. YOUNG
 EDWARD B. MAXWELL, 2ND
 JOSY W. INGERSOLL

September 3, 2008

**REDACTED -
PUBLIC VERSION**

The Honorable Mary Pat Thyng
 J. Caleb Boggs Federal Building
 844 North King Street
 Wilmington, DE 19801

Re: Roquette Freres v. SPI Pharma, Inc., et al., C.A. No. 06-540 (GMS)(MPT)

Dear Judge Thyng:

On behalf of Defendant SPI Pharma, Inc. ("SPI"), I write with background about the discovery dispute teleconference scheduled for this Friday, September 5, 2008 at 12:15 p.m. (D.I. 191).

The dispute concerns requests for the production of documents and inspection of testing equipment made by SPI on the record during the August 8 deposition of Roquette Freres' ("Roquette") technical expert witness, Dr. Harry Brittain, and subsequently memorialized in an August 11 letter to counsel for Roquette. (Exhibit A). As explained below, the requested documents and SPI's inspection of Dr. Brittain's laboratory equipment are relevant to SPI's noninfringement defense and affirmative counterclaim of invalidity based on indefiniteness.

The patent-in-suit claims a pulverulent mannitol having a friability of about 40% to about 80% when measured according to a "Test I" protocol. Dr. Brittain recently conducted a friability test on SPI's Mannogem™ EZ – one of the accused products – [REDACTED]

[REDACTED] SPI first became aware that Dr. Brittain conducted this experiment on the day of his deposition. SPI's counsel was handed at deposition a two-page lab notebook entry reflecting Dr. Brittain's recent experiment on Mannogem™ EZ, which was marked as Defendant's Exhibit ("DX") 38. (Exhibit B). DX 38 and the deposition testimony [REDACTED]

[REDACTED] attached hereto as Exhibit

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C). SPI immediately requested the manuals and literature associated with this instrumentation and an opportunity to inspect the equipment, but Roquette has consistently refused.

SPI should be provided with this limited discovery for all of the following reasons:

- Documents associated with the testing equipment should have already been produced by Roquette in response to SPI's Document Request Nos. 9 ("documents and things relating to...any testing...on the EZ product") and 11 ("documents and things relating to...any testing... relating to the subject matter of the patent-in-suit including, but not limited to, the test methods associated with 'Test I'");
- The requested documents and inspection of laboratory testing equipment are relevant in [REDACTED] This information further strengthens SPI's noninfringement defense and SPI is entitled to its production;
- At the heart of SPI's contention that the patent-in-suit is invalid for indefiniteness is the notion that the claims of the patent-in-suit lack specificity concerning the friability testing procedure. For example, the Test I protocol does not specify the type of drum to be used with the Erweka friabilator. [REDACTED]
[REDACTED]
[REDACTED] The operating manual, instruction guide, and any and all documents associated with the equipment used by Dr. Brittain are thus highly relevant to SPI's indefiniteness argument;
- Roquette has already produced the Operating Instructions for the Hosokawa Powder Characteristics Tester (RF 1336-60, Exh. D), which Dr. Brittain used in measuring various properties of the accused products in this case. Roquette also has produced product literature concerning the Erweka friabilator (RF 500-01, DX 41, Exh. E attached hereto), but not the instructions or operating manuals. By doing so, Roquette acknowledged that documents associated with the testing equipment used to measure the various properties claimed in the patent-at-issue are relevant and responsive to SPI's document requests. Roquette should not be allowed to selectively determine which equipment documentation it will produce; and
- SPI made its request for the production of documents and things associated with Roquette's testing equipment in a timely manner. SPI's requests were made on the record during Dr. Brittain's deposition when it first learned that additional testing had been conducted. SPI memorialized its requests in writing on August

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11, well before the close of expert discovery on August 15. Roquette cannot deny SPI's requests on the basis of delay or because discovery has since concluded.

SPI respectfully asks Your Honor to compel Roquette to produce all documents concerning the Erweka friabilator and Gilson Ro-Tap used during Dr. Brittain's testing of the accused products, and allow SPI's counsel an opportunity to inspect this equipment at the earliest possible date.

Respectfully submitted,



Jeffrey T. Castellano (No. 4837)

JTC:mmeh

Attachments

cc: Clerk, U.S. District Court (By Hand Delivery)
Mary B. Graham, Esq. (By E-mail and Hand Delivery)
Julia Heaney, Esq. (By E-mail and Hand Delivery)
Douglas V. Rigler, Esq. (By E-mail)